



Patent  
Attorney Docket No. 019019-009

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Paolo Alberto Veronesi et al.

Group Art Unit: 1614

Application No.: 10/516,613

Examiner:

Filing Date: December 3, 2004

Confirmation No.: 7113

Title: NASAL PEPTIDE PHARMACEUTICAL FORMULATION

SECOND  
INFORMATION DISCLOSURE STATEMENT  
TRANSMITTAL LETTER

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Enclosed is a SECOND Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

- No additional fee for submission of an IDS is required.
- The fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- A statement under 37 C.F.R. § 1.97(e) is also enclosed.
- A statement under 37 C.F.R. § 1.97(e), and the fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) are also enclosed.
- Charge \_\_\_\_\_ to Deposit Account No. 02-4800 for the fee due.
- A check in the amount of \_\_\_\_\_ is enclosed for the fee due.
- Charge \_\_\_\_\_ to credit card. Form PTO-2038 is attached.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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Alexandria, Virginia 22313-1404  
(703) 836-6620

Date: May 31, 2005

By Mary Katherine Baumeister  
Mary Katherine Baumeister  
Registration No. 26,254



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of )  
Paolo Alberto VERONESI et al. ) Group Art Unit: 1614  
Application No.: 10/516,613 ) Examiner:  
Filed: December 3, 2004 ) Confirmation No.: 7113  
For: NASAL PEPTIDE PHARMACEUTICAL )  
FORMULATION )  
)  
)

## SECOND INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, the accompanying information is being submitted in accordance with 37 C.F.R. §§ 1.97 and 1.98. Applicants request consideration of the documents listed on the accompanying Form PTO-1449. These documents are cited in the instant specification, or are English-language counterparts thereof.

Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed. However, copies of the listed U.S. patents are not enclosed since it is no longer required according to the July 11, 2003 waiver of the requirement for copies of cited U.S. patents and U.S. patent application publications in national patent applications filed after June 30, 2003 and international applications entering the national stage under 35 U.S.C. § 371 after June 30, 2003.

All of the cited documents are in English except for those specifically noted below:

DE 2256445 is in German. Its English-language counterpart, Wissmann et al. U. S. Patent No. 3,931,141, is cited to serve as an English translation.

BE 860717 is in French. Its English-language counterpart, GB 1539318, is provided to serve as an English translation.

JP 55055120 is in Japanese. The accompanying patent family search indicates there are no English-language counterparts. Applicants do not have an English translation of this document; however, the patent family search provides an English-language abstract which serves as a brief statement of relevance, as does the instant specification, page 3, lines 18-30.

**FIRST** Information Disclosure Statement  
Application No. 10/516,613  
Attorney's Docket No. 019019-009  
Page 2

The article in the Journal of the Diabetic Society is in Japanese. Applicants do not have an English translation. The instant specification provides a brief statement of relevance; see page 2, line 30 to page 3, line 4.

The Chevance et al. Acta Otolaryng. Article is in French. However, there is an English-language summary on page 27 of the reference which serves as a brief statement of relevance, as does the paragraph at page 3, line 31 to page 4, line 8 of the instant specification.

This statement, Form PTO-1449 and enclosed documents are being submitted within three (3) months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later. Since these documents are being filed within the time period set forth in 37 C.F.R. § 1.97(b), no fee or statement is required. In the event that an Action on the merits has in fact already issued, the Commissioner is authorized by the accompanying Information Disclosure Statement Transmittal Letter to charge any necessary fee to counsel's deposit account so that this statement will be considered.

It is respectfully requested that the Examiner consider this statement and cited documents and that an Examiner-initialed copy of the accompanying Form PTO-1449 be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date May 31, 2005

By: Mary Katherine Baumeister  
Mary Katherine Baumeister  
Registration No. 26,254

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Substitute for form 1449A/PTO & 1449B/PTO			
<b>SECOND INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>			
(use as many sheets as necessary)			
Sheet	1	of	2
		<b>Complete if Known</b>	
		Application Number	
		10/516,613	
		Filing Date	
December 3, 2004			
First Named Inventor			
Paolo Alberto Veronesi et al.			
Examiner Name			
Attorney Docket Number			
019019-009			

## **U.S. PATENT DOCUMENTS**

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	STATUS		
					IPER	Cited in Spec	Abstract
	99/59543	A1	WO	11-25-1999		X	X
	0122036	A1	EP	10-17-1984		X	X
	0094157	A1	EP	11-16-1983		X	X
	0302772	A1	EP	02-08-1989		X	X
	0468182	A1	EP	01-29-1992		X	X
	2256445		DE	05-22-1974	X <sup>1</sup>		X
	860717		BE	11-30-1977	X <sup>2</sup>		X
	1539318		GB	01-31-1979			
	55055120	A	JP	04-22-1980		X	X

## **NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	Nishihata et al., <i>J. Pharm. Pharmacol.</i> , 33, 334-335(1981), The Pharmaceutical Society of Great Britain, Pharmaceutical Press, London, GB.
	Wigley et al., <i>Diabetes</i> , vol. 20, no. 8, 552-556,(1971), the American Diabetes Association, Alexandria, VA.
	<i>Journal of the Diabetic Society</i> , Summary, 237 (1974), Japan Diabetes Society, Tokyo, JP.
	Lemp et al., <i>Amer. J. Ophthalmol.</i> 105, 6 (1988), 670-673, Elsevier, Inc., New York, NY.
	Bruynzeel et al., <i>Contact Dermatitis</i> , 17, 1 (1987), 41-42, Blackwell Munksgaard, Copenhagen, DK.

**Examiner Signature** \_\_\_\_\_ **Date Considered** \_\_\_\_\_

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

<sup>1</sup>See English-language counterpart, Wissmann et al. U. S. Patent No. 3,931,141.

<sup>2</sup>See English-language counterpart, GB1539318.

MAY 31 2005

**SECOND  
INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 2

<i>Complete if Known</i>	
<b>Application Number</b>	10/516,613
<b>Filing Date</b>	December 3, 2004
<b>First Named Inventor</b>	Paolo Alberto Veronesi et al.
<b>Examiner Name</b>	
<b>Attorney Docket Number</b>	019019-009



**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	Fisher, <i>Cutis</i> , 39, 5(1987), 381-383, Quadrant HealthCom, Chatham, NJ.
	Chevance et al., <i>Acta Otolaryng.</i> 70 (1970), 16-28, Taylor & Francis AB, Stockholm, SE.
	<i>The Merck Index</i> , ed. Susan Budavari et al., twelfth edition (1996), entry no. 2148, p.350, Merck & Co., Inc., Whitehouse Station, NJ.
	Dua et al., <i>International Journal of Pharmaceutics</i> , 147 (1997), 233-242, Elsevier BV, Amsterdam, NL.
	Felber et al. <i>Experientia</i> 25, 11 (1969), 1195-1196, Birkhäuser Verlag, Basel, CH.
	Gennser et al., <i>The Lancet</i> , 1, No. 7862 (1974), 865, Little, Brown and Company, Boston, MA.
	Greenberg et al., <i>Antimicrobial Agents and Chemotherapy</i> , Vol. 14, No. 4 (1978), 596-600, American Society for Microbiology, Washington, D.C.
	Bergquist et al., <i>The Lancet</i> , 2, No. 8136 (1979), 215-217, Little, Brown and Company, Boston, MA.
	Pontiroli et al., <i>British Medical Journal</i> , Vol. 284, 6312 (1982), 303-306, BMJ Publishing Group, London, GB.
	<i>Aerosols in Medicine</i> , ed. F. Morén et al. second, revised edition (1993), 346, Elsevier Science Publishers B.V., Amsterdam, NL.

Examiner Signature	Date Considered
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